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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,698	07/13/2001	Gary Ketner	03940055aa	4755

30743 7590 10/28/2002

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EXAMINER
PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/904,698	Ketner
Examiner	**Art Unit**
Scott D. Priebe, Ph.D.	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 28, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *6-18* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *6-18* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 17 and 18 are of improper dependent form for failing to further limit the subject matter of claims 1 and 11, respectively as per 37 CFR 1.75(c). The physical act of introducing a protein into a cell is not the same as introducing a polynucleotide into a cell. In the latter, the protein is made in the cell and by the cell. Different methods and materials are used for delivering protein and polynucleotides. Consequently, claims 17 and 18 have been treated as independent claims for the purpose of restriction.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 6 and 7, drawn to a method for preventing cancer by introducing adenovirus E4 orf6 protein (E4 34k) into cells, classified in class 514, subclass 2.

II. Claims 6 and 8, drawn to a method for treating cancer by introducing E4 34k into cancer cells, classified in class 514, subclass 2.

III. Claims 6 and 9, drawn to a method for preventing concatemerization of wild-type adenoviral DNA by introducing E4 34k into a cell comprising the adenoviral DNA, classified in class 435, subclass 325.

IV. Claims 6 and 10, drawn to a method for inhibiting V(D)J recombination in a cell of the immune system by introducing E4 34k into the immune system cell, classified in class 435, subclass 325.

V. Claim 11, drawn to a method for preventing apoptosis induced by viral replication by introducing E4 34k into a cell, classified in class 435, subclass 325.

VI. Claims 6 and 12-16, drawn to a method for increasing the efficiency of chemotherapeutic or radiation treatment of cancer by introducing E4 34k into cancer cells in conjunction with the chemotherapeutic or radiation treatment, classified in class 514, subclass 1+, depending upon chemotherapeutic agent.

VII. Claim 17, drawn to a method for inhibiting double-strand break repair (DSBR) by introducing a polynucleotide which encodes E4 34k into a cell, classified in class 435, subclass 455.

VIII. Claim 18, drawn to a method for preventing apoptosis induced by viral replication by introducing a polynucleotide which encodes E4 34k into a cell, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Inventions I-IV and VI-VII and inventions V and VIII are unrelated, as they are not disclosed as capable of use together, and have different modes of operation, and different functions and effects. According to the specification, invention V and VIII operate by inhibiting induction of p53-dependent apoptosis pathways in response to viral replication, whereas I-IV and VI-VII operate by blocking DSB repair.

Inventions I, II, and VI and inventions III and IV are unrelated. Inventions I, II and VI are directed to methods of prophylactic or therapeutic treatment of cancer in individuals. These methods have different functions and effects from inventions III and IV, and are not disclosed as being usable together.

Inventions I, II and VI are unrelated to each other. Invention I is directed to treating all cells of an individual with E4 34k for prevention of cancer, presumably by blocking DSBR events that would involve illegitimate recombination leading to oncogenic mutation. Inventions II and VI are directed to treating individuals that have cancer and the E4 34K is delivered to specifically to cancer cells. In treating different individuals, invention I and inventions II and VI are not disclosed as being used together. In treating different cell populations in the individuals, invention I and inventions II and VI have different functions and effects. Inventions II and VI differ by whether the E4 34k treatment is conjoined with chemotherapeutic or radiation treatment, which induces DSBs. How invention II would be used to treat cancer is unclear. The specification discloses that impaired DSBR predisposes an individual to cancer, and proposes that cellular proteins homologous to E4 34k may represent a class of oncogene (page 44).

Furthermore, E4 34k protein blocks induction of p53-dependent apoptosis, impairment of p53 is known in the art to predispose a cell to oncogenesis, and restoration of p53 function by gene therapy is currently being tested for treatment of cancer. Based upon this disclosure, the effect of invention II would appear to be to make a cancer more malignant or aggressive by increasing the predisposition to cancer and by blocking p53-dependent pathways that prevent oncogenesis of a cell by induction of apoptosis. In contrast, invention VI would be directed at killing cancer cells by impairing repair of DSBs induced by the chemotherapeutic or radiation treatment. Thus, the effects of inventions II and VI are different.

Inventions III, IV and VII are unrelated to each other. Each method is directed to different purposes (functions), uses different cells, and are not disclosed as being used together.

Inventions I-IV and VI and invention VII are unrelated. Inventions V and VIII are unrelated. Inventions I-VI are directed to delivery of E4 34k protein, whereas inventions VII and VIII are directed to delivery of a polynucleotide that following introduction into the cell will express E4 34k protein. Thus chemically and biologically different products are used in these two groups of inventions, and the steps to introduce these different products have different modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups, and have acquired a separate status in the art

because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 6 link(s) inventions I-IV and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 6. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is (703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

Scott D. Priebe, Ph.D.
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Technology Center 1600
Art Unit 1632